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EQUITY RESEARCH
Company Report

March 28, 2017

Cara Therapeutics (CARA - $18.15)

Healthcare/Biotechnology

Ticker:	**CARA**
Rating:	**Buy**
Price Target:	**$35**

CARA Pruritus Data Hits All Endpoints – Raising PT to $35

This morning before the open CARA reported the data from their 174 patient Phase 2b trial of IV CR845 for moderate to severe pruritus in dialysis patients (UP). The data looks pretty good to us, hitting both the primary (p=0.0019) and secondary (p=0.0007) endpoints with solid statistical significance. Interestingly there wasn't dose-response in the trial across the 0.5/1.0/1.5 mcg/kg arms, typically not a great sign, but likely due to the oversaturation of the kappa opioid receptor at even the lowest 0.5 mcg/kg dose (see Figure 3 later in this report). Additionally, the drug remains very safe with a solid safety profile in the Phase 2b trial. Next steps for CARA include meeting the FDA in an end-of-Phase 2 meeting (anticipated mid-2017) and seeing if the FDA will consider this Phase 2b data sufficient as one of the pivotal Phase 3 trials, necessitating only one additional Phase 3 trial before filing. We see this data as a huge positive for CARA given the significant unmet medical need in treating pruritus, and we see this as the potentially "blockbuster" indication for CR845, which is also being tested for post-operative pain and osteoarthritis of the knee pain, with data expected on those indications (and an oral pruritus version) in 2H17. We are reiterating our Buy rating and raising our PT from $20 to $35.

1. **IV CR845 for UP hit statistical significance with a purpose.** CR845 demonstrated efficacy in reduction of itch (NRS) and improvement in quality of life (Skindex-10) at 8 weeks with p=0.0019 and p=0.0007, respectively. With CR845 hitting on both endpoints, demonstrating lasting effect over time and a clean AE profile, we see CARA has potentially only having to run one Phase 3 if the FDA accepts the Phase 2b data as a Phase 3.
2. **One catalyst down, 2017 is far from over.** CARA still expects Phase 3 IV CR845 for post-operative pain, Phase 2b oral CR845 for hip/knee osteoarthritis pain data, and Phase 1 oral CR845 for UP data in 2Q17. As CR845 has the potential to be as effective as Oxycontin in a Schedule 5 drug (or even unscheduled), we continue to see significant value in these programs.
3. **Reiterate Buy rating, raising price target to $35.** We value CARA on a sum-of-the-parts: IV CR845 for pruritus: $14/share, IV/oral post-op pain: $12/share, oral pruritus: $7/share, and cash (end '17) and tech: $2/share.

Trading Data:

Last Price (03/27/2017)	$18.15
52–Week High (06/27/2016)	$19.44
52–Week Low (03/03/2017)	$4.35
Market Cap. (MM)	$495.6
Shares Out. (MM)	27.3

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	NA	NA	NA	NA	(2.05)	NA
FY-17E	(0.76)	(0.68)	(0.44)	(0.37)	(2.20)	NA
FY-16A	(0.39)	(0.48)	(0.42)	(0.81)	(2.10)	NA
FY-15A	(0.21)	(0.25)	(0.23)	(0.35)	(1.05)	NA

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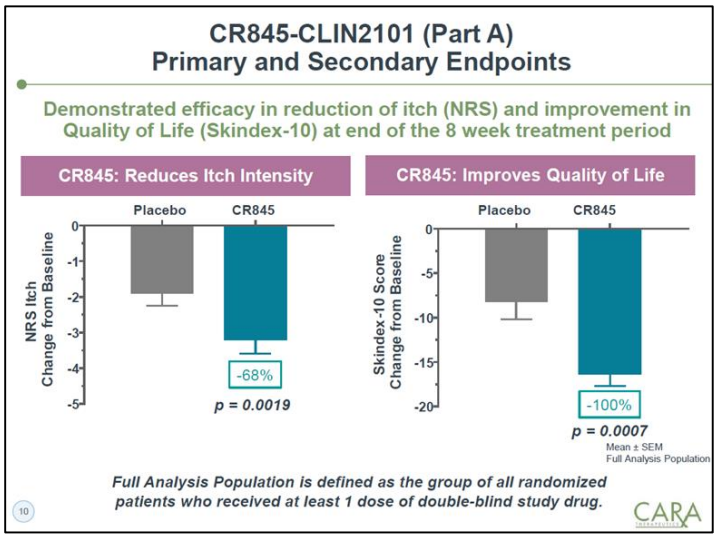
Figure 1: Valuation

Sum-of-the-parts value: CARA		
Segment	Valuation (000's)	Per share value
CR845 - IV uremic pruritus	$438,074	$14.0
CR845 - IV post-op pain	$286,919	$9.0
CR845 - oral general pruritus	$235,930	$7.0
CR845 - oral OA pain	$100,094	$3.0
Cash (end '17) & tech value	$62,388	$2.0
SUM	**$1,123,405**	**$35**
Shares out '17E (000)		32,233

Source: Company presentation

CR845 demonstrated solid & meaningful reductions in both the Numeric Ratings Score (NRS) worst itch intensity (the primary endpoint) the Skindex-10 Quality of Life measurements (the secondary endpoint).

Figure 2: Primary & Secondary Endpoints



Source: Company presentation

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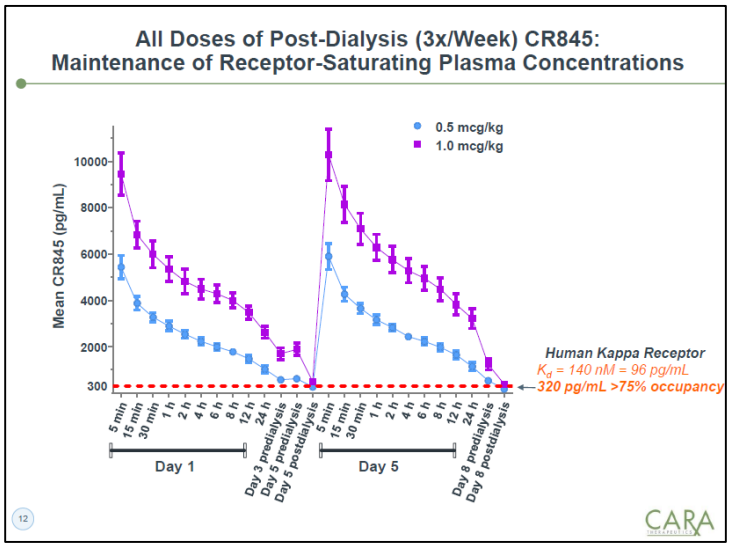
Due to the high receptor occupancy of CR845 to the Kappa receptor (see the 0.5 mcg/kg and 1.0 mcg/kg doses below) there wasn't dose-response shown in the data as all doses saturated the receptor.

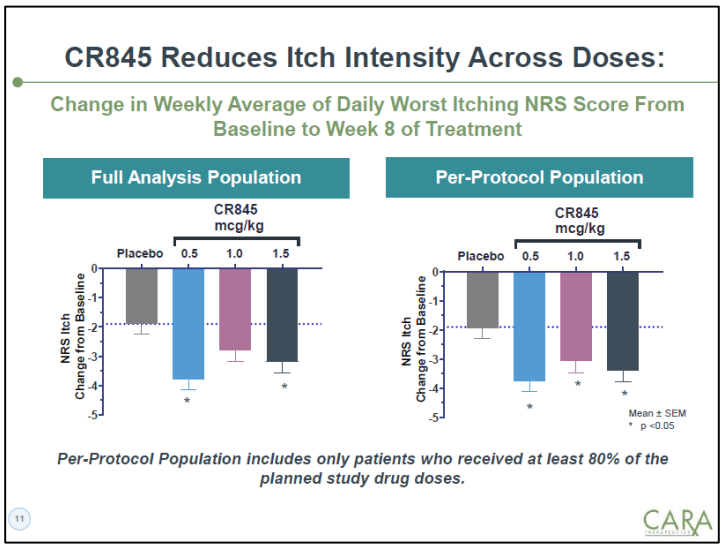
Figure 3: CR845 Receptor Occupancy Saturates Dose-Response



Source: Company presentation

The below data shows the lack of dose-response in the primary endpoint for the treatment arms. The 1 mcg/kg arm in the full analysis group includes patients who dropped per protocol, hence missing stat. sig. In the per-protocol population all 3 arms hit statistical significance.

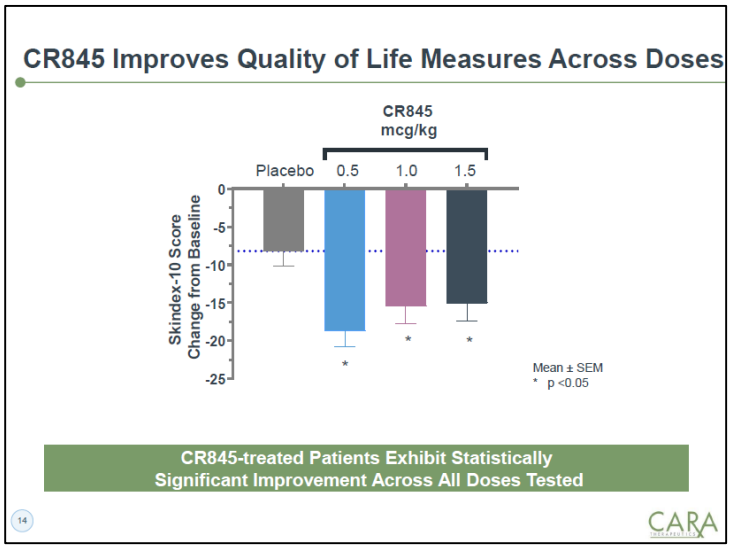
Figure 4: Primary Endpoint Across Doses



Source: Company presentation

The below data shows the lack of dose-response in the secondary endpoint for the treatment arms. CARA will likely advance the 0.5 mcg/kg and the 1.0 mcg/kg arms into the next Phase 3 trial.

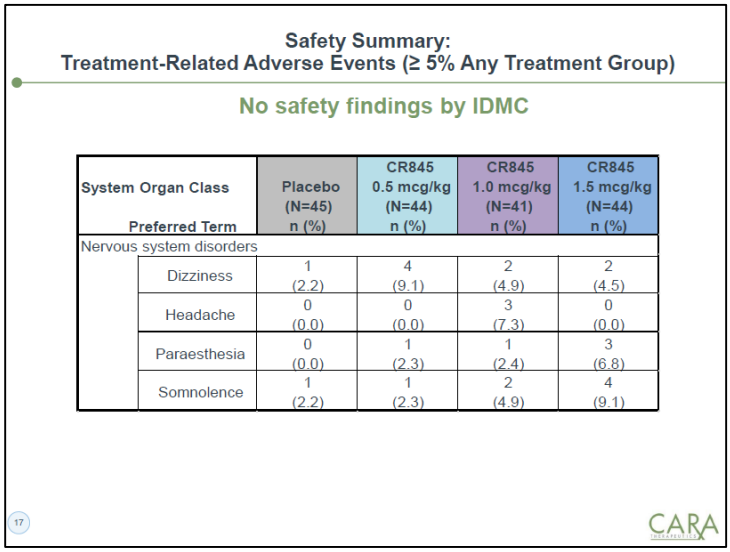
Figure 5: Secondary Endpoint Across Doses



Source: Company presentation

The safety data shows a clean profile.

Figure 6: Solid Safety Profile



System Organ Class / Preferred Term	Placebo (N=45) n (%)	CR845 0.5 mcg/kg (N=44) n (%)	CR845 1.0 mcg/kg (N=41) n (%)	CR845 1.5 mcg/kg (N=44) n (%)
Nervous system disorders				
Dizziness	1 (2.2)	4 (9.1)	2 (4.9)	2 (4.5)
Headache	0 (0.0)	0 (0.0)	3 (7.3)	0 (0.0)
Paraesthesia	0 (0.0)	1 (2.3)	1 (2.4)	3 (6.8)
Somnolence	1 (2.2)	1 (2.3)	2 (4.9)	4 (9.1)

Source: Company presentation

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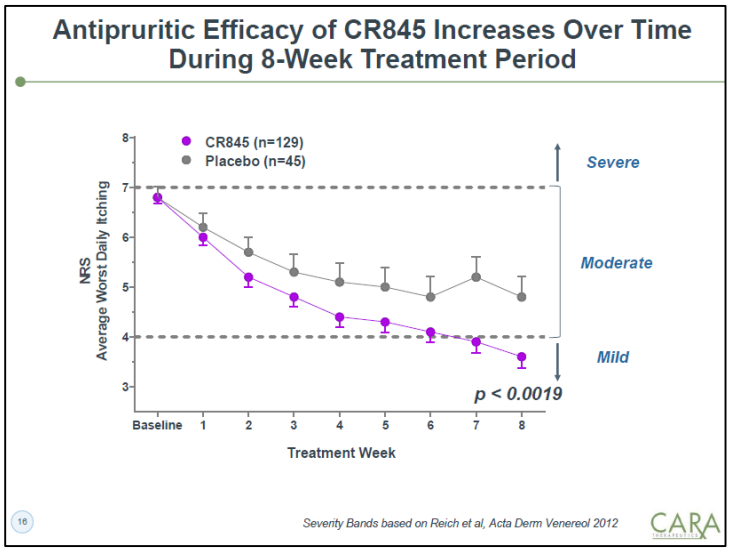
CARA will run a 12-week trial next, and the 8-week data appears to show a durability of effect that should continue to build in the 12-week trial. CARA will also conduct a 1-year open label extension.

Figure 7: Durability of Effect



Source: Company presentation

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Figure 7: Quarterly Income Statement

CARA Therapeutics
Quarterly income statement

($000 except per share)	2016A 1QA	2016A 2QA	2016A 3QA	2016A 4QA	2016A Year	2017E 1QE	2017E 2QE	2017E 3QE	2017E 4QE	2017E Year
Revenues										
License & milestones					$0					
Collaborative revenues	$7	$79			86	$750	$750	$750	$750	3,000
Total Revenue	**$7**	**$79**	**$0**	**$0**	**$86**	**$750**	**$750**	**$750**	**$750**	**$3,000**
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	**7**	**79**	**-**	**-**	**86**	**750**	**750**	**750**	**750**	**3,000**
Research and development	8,546	10,760	9,671	20,277	49,254	20,000	18,000	12,000	9,750	59,750
General and administrative	2,447	2,645	2,102	2,038	9,232	2,000	2,250	2,750	3,000	10,000
Total operating expenses	10,993	13,405	11,773	22,315	58,486	22,000	20,250	14,750	12,750	69,750
Income (loss) from Operations	**(10,986)**	**(13,326)**	**(11,773)**	**(22,315)**	**(58,400)**	**(21,250)**	**(19,500)**	**(14,000)**	**(12,000)**	**(66,750)**
Interest income (expense), net	149	172	176	155	652	25	25	25	25	100
Other (exp) gain, net										
Income (loss) before taxes	**(10,837)**	**(13,154)**	**(11,597)**	**(22,160)**	**(57,748)**	**(21,225)**	**(19,475)**	**(13,975)**	**(11,975)**	**(66,650)**
Income tax exp (benefit)	(145)	(79)	(55)	(189)	(468)					
Net income (Loss)	**(10,692)**	**(13,075)**	**(11,542)**	**(21,971)**	**(57,280)**	**(21,225)**	**(19,475)**	**(13,975)**	**(11,975)**	**(66,650)**
Net income to common										
Earning per Share (EPS)	**($0.39)**	**($0.48)**	**($0.42)**	**($0.81)**	**($2.10)**	**($0.76)**	**($0.68)**	**($0.44)**	**($0.37)**	**($2.20)**
Adj EPS ex-1x & non-cash			**($0.42)**		**($2.10)**					
Weighted avg. shares (000)	27,260	27,283	27,283	27,291	27,279	27,833	28,433	32,033	32,633	30,233
Fully diluted shares (000)	29,474	29,540	29,582	30,712	29,827	29,833	30,433	34,033	34,633	32,233

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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Figure 8: Annual Income Statement

CARA Therapeutics
Annual income statement

($000 except per share)	2016A	2017E	2018E	2019E	2020E	Comments
Revenues						
CR845 - IV post-op pain					$56,760	Interim data 2Q17
CR845 - IV Uremic pruritus			-	-	17,938	p2 data 1Q17
CR845 - oral hip/knee OA pain			-	-	-	p2b data 2Q17
License & milestones	$0		-	-	-	Maruishi milestones here
Collaborative revenues	86	$3,000	$3,000	$3,000	3,000	
Total Revenue	**$86**	**$3,000**	**$3,000**	**$3,000**	**$77,698**	
Expenses:						
Cost of Revenue (COGS)	-	-	-	-	8,514	
Gross Margin	**86**	**3,000**	**3,000**	**3,000**	**69,184**	
R&D	49,254	59,750	60,500	58,250	50,500	
SG&A	9,232	10,000	10,750	11,000	30,000	50 reps in 2020
Total op exp	58,486	69,750	71,250	69,250	80,500	
Inc/(loss) from Ops	**(58,400)**	**(66,750)**	**(68,250)**	**(66,250)**	**(11,316)**	
Int income (exp), net	652	100	100	100	100	
Other expenses, net	-	-	-	-	-	
Inc/(loss) before taxes	**(57,748)**	**(66,650)**	**(68,150)**	**(66,150)**	**(11,216)**	
Income tax exp (benefit)	(468)	-	-	-	-	sig. tax loss carryforwards
Net income (Loss)	**($57,280)**	**($66,650)**	**($68,150)**	**($66,150)**	**($11,216)**	
Net income to common						
Earning per Share	**($2.10)**	**($2.20)**	**($2.05)**	**($1.85)**	**($0.30)**	
Adj EPS ex-1x & non-cash	**($2.10)**					
Weighted avg. shares (000)	27,279	30,233	33,233	35,733	37,233	
Fully diluted shares (000)	29,827	32,233	35,733	38,483	39,983	
Cash position	$58,276	$37,388	$29,570	$26,103	$17,996	Additional raises 2017-2019

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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Major Risks

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

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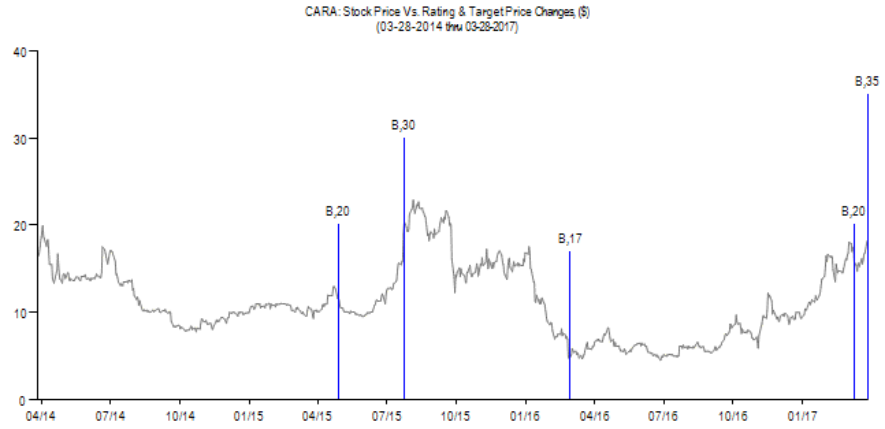
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
04/28/2...	Buy (B)	11.59

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
04/28/2...	20.00	11.59
07/24/2...	30.00	20.43
02/29/2...	17.00	4.92
03/10/2...	20.00	15.84
03/28/2...	35.00	18.15*

** Previous Close3/27/2017*

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	63.41%	29.27%	2.44%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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